DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 20, 2015

NxStage Medical, Inc.
Randall J. Covill
Manager, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K143313
Trade/Device Name: NxStage® Therapeutic Plasma Exchange (TPE) Cartridge
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, LKN
Dated: February 24, 2015
Received: February 25, 2015

Dear Randall J. Covill,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K143313

Device Name: NxStage® Therapeutic Plasma Exchange (TPE) Cartridge

Indications for Use: The NxStage TPE Cartridge is indicated for use only with the NxStage System One for therapeutic plasma exchange in a clinical environment.

All treatments must be administered under a physician's prescription, and must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician.

Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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NxStage Medical, Inc.
NxStage Therapeutic Plasma Exchange Cartridge
510(k) Premarket Notification

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: November 18, 2014

B. Submitter's Information:

Name:	NxStage Medical, Inc.
Address:	350 Merrimack Street Lawrence, MA 01843
FDA Establishment Owner/Operator Number:	9045797
Contact Person:	Randall J. Covill Manager, Regulatory Affairs
Phone:	(978) 298-4163
Fax:	(978) 687-4750
Manufacturer:	NxStage Medical, Inc. 350 Merrimack Street Lawrence, MA 01843
FDA Establishment Registration Number:	3003464075
Sterilization Site:	Steris Isomedix (NxStage Cartridge) 1000 S. Sarah Place Ontario, CA 91761

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C. Device Name:

Trade/Proprietary Name:	NxStage Therapeutic Plasma Exchange Cartridge
Common/Usual Name:	High Permeability Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	KDI
	LKN
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Legally Marketed Predicate Device

NxStage TPE Cartridge, 510k number K093069 cleared on October 23, 2010

E. Device Description/Indications for Use:

The NxStage TPE Cartridge provides therapeutic plasma exchange therapy when used with a commercially available TPE filter. The blood tubing set is the NxStage TPE Cartridge. The TPE Cartridge is a single use extracorporeal blood circuit and fluid management device available without a pre-attached filter. Therapeutic plasma exchange requires the use of a commercially available Therapeutic Plasma Exchange filter such as such as the Asahi Plasmaflo OP-05W (A) wet filter (PMA P820033 S005 approved on March 16, 2010).

Indications for use:

The NxStage TPE Cartridge is indicated for use only with the NxStage System One for therapeutic plasma exchange in a clinical environment.

All treatments must be administered under a physician's prescription, and must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician.

F. Comparison of Technological Characteristics with the Predicate Device:

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the predicate NxStage TPE Cartridge (510k number K093069 cleared on October 23, 2010) when used with a commercially available plasma filter such as the Asahi Plasmaflo OP-05W (A) wet filter (PMA P820033 S005 approved on March 16, 2010). The proposed device is designed with similar components and features as used in the predicate device as shown below in Table 1.

Table 1
Comparison of Technological Characteristics with the Predicate Device

Parameter	Proposed Device NxStage TPE Cartridge (Subject of this 510K)	Predicate NxStage TPE Cartridge (K093069)
Intended Use	Therapeutic Plasma Exchange	Therapeutic Plasma Exchange
Technology / Components Plasma separator filter used	Asahi Plasmaflo OP-05W (A) wet filter (PMA P820033 S005 approved on March 16, 2010)	Asahi Plasmaflo AP-05H(L) dry filter (PMA P820033 approved on January 8, 1986)
Blood volume	Same	55 ml nominal, exclusive of filter
Blood pump segment internal diameter	Same	8 mm (0.315 in)
Patient line internal diameter	Same	3.1 mm (0.122 in)
Maximum venous pressure	Same	400 mmHg at all flow rates
Therapy fluid flow rates	0.1 to 4.0 L/hr	0.1 to 3.6 L/hr
Input infusion temperature range	Same	15º to 37º C
Sterilization method	Same	Gamma 10^{-6} SAL
Non-Pyrogenic	Same	Yes, (LAL)

G. Performance Data

The following tables outline the testing performed on the CAR-510-C to support the determination of substantial equivalence to the predicate device.

Table 2
Performance and Functional Testing Per FDA Guidance for Industry and FDA Staff: Hemodialysis Blood Tubing Sets

Test Method	Test Objective	Result
Pressure leak testing demonstrating the blood tubing can withstand pressures up to 1.5 times the maximum labeled positive and negative pressures	Ensure that the blood tubing is capable of withstanding extreme positive and negative pressure conditions	Pass – Results within acceptance criteria
Endurance testing of pump segment at maximum labeled blood flow rates and pressures	Ensure that pump segment is capable of withstanding maximum labeled blood flow rates and pressures	Pass – Results within acceptance criteria
Endurance testing under both positive and negative pressures of any injection ports (if applicable) using the largest recommended gauge needle identified in the labeling	Ensure that injection ports are capable of withstanding both positive and negative pressures	Pass – Results within acceptance criteria
Priming volume assessment	To assess and measure the priming volume	Pass – Results within acceptance criteria
Tensile testing of joints and materials of all tubing segments	Ensure that tubing failure (leaking) does not occur	Pass – Results within acceptance criteria

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Table 2
Performance and Functional Testing Per FDA Guidance for Industry and FDA Staff: Hemodialysis Blood Tubing Sets

Test Method	Test Objective	Result
The ability of pressure transducers to withstand leakage when subject to pressures up to 2 times the maximum labeled pressure e.g. "strikethrough"	Ensure that pressure transducers withstand leakage when subject to pressures up to 2 times the maximum labeled pressure	Pass – Results within acceptance criteria
Performance testing to evaluate the ability of tubing to resist kinking after repeated clamping, particularly in the post-pump tubing segment	Ensure that tubing failure (kinking) does not occur	Pass – Results within acceptance criteria
Performance testing of the device's clamps to demonstrate that they can successfully occlude blood tubing	Ensure that device clamps can successfully occlude the blood tubing	Pass – Results within acceptance criteria
Hemocompatibility (i.e. mechanical hemolysis) for new or significantly altered hemodialysis tubing design that affects the pattern of blood flow	Evaluate the hemolytic properties of the device	Pass – Results within acceptance criteria

Table 3 **Packaging Qualification and Ship Testing**		
Test Method	Test Objective	Result
Structural integrity testing on gamma sterilized and thermally stressed samples. ISTA 2A ship testing.	Ensure that the package design is robust and prevents product damage.	Pass – Results within acceptance criteria

Biocompatibility Testing

The biocompatibility evaluation for the NxStage TPE Cartridge was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process," as recognized by the FDA. The battery of testing included the following tests.

- Cytotoxicity
- Hemolysis
- USP Physicochemical
- FTIR

Conclusion: Results of the non-clinical testing have demonstrated that the proposed NxStage TPE cartridge is substantially equivalent to the predicate device and is suitable for the labeled indications for use.